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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/688,672 | 10/10/2000 | Yasir Skeiky | 014058-009041US | 2671 |

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EXAMINER

SWARTZ, RODNEY P

ART UNIT PAPER NUMBER

1645

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/688,672

Applicant(s)

SKEIKY ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 June 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see Detailed Action.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Final Office Action, received 20 June 2005, is acknowledged.
2. Claims 1-8, 11-27, 105-109, and 111-115 are pending and under consideration.

Rejections Maintained

3. The rejection of claims 5 and 19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Pat. No. 6,592,877, is maintained for reasons of record.

Applicants argue that claims 1-3 of U.S. Pat. No. 6,592,877 is an isolated fusion protein comprising four *M. tuberculosis* antigens: TbRa3, Tb38-1, TbH4, and 38kD. In contrast, claim 5 of the instant application is directed to a composition containing a fusion protein comprising *M. tuberculosis* antigens MTb81 and Mo2. Claim 5 relates to a fusion protein comprising 2 antigens different from the 4 antigens in claims 1-3 of U.S. Pat. No. 6,592,877.

The examiner has considered applicants' argument, but does not find it persuasive. Claim 5 depends from claim 4, not claim 1. Claim 4 is drawn to a composition comprising an isolated TbRa3 antigen, an isolated 38kD antigen, an isolated Tb38-1 antigen, and an isolated FL TbH4 antigen, and a pharmaceutically-acceptable excipient. Claim 5 is the composition of claim 4 wherein the antigens are covalently linked, thereby forming a fusion polypeptide. Thus, contrary to applicants' argument, claim 5 is drawn to a fusion polypeptide comprising all four of the antigens listed claims 1-3 of U.S. Pat. No. 6,592,877.

Applicants argue that the instant claims are drawn to an antigen "FL TbH4" while claims 1-3 of U.S. Pat. No. 6,592,877 are drawn to an antigen "TbH4". The sequence of FL TbH4 is SEQ ID NO:12, 286 amino acids in length, while TbH4 is SEQ ID NO:89, 166 amino acids in

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length. Thus, since the lengths of TbH4 and FL TbH4 are different, the fusion polypeptide of the instant invention is not obvious over claims 1-3 of U.S. Pat. No. 6,592,877.

The examiner has considered applicants' argument, but does not find it persuasive. The instant claims are directed to a fusion polypeptide comprising four antigens designated only by name. Thus, in the absence of any designated sequence in the instant claims, FL TbH4 is an obvious variant of TbH4, i.e., it is all of a polypeptide comprising an already claimed sequence.

4. The rejection of claim 6 under 35 U.S.C. 112, second paragraph, indefiniteness for rejection from a rejected claim, is maintained for reasons of record.

Conclusion

5. Claims 5, 6, and 19 remain finally rejected. Claims 1-4, 7, 8, 11-18, 20-27, 105-109, and 111-115 appear to be allowable.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P. SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

October 5, 2005